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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,415	10/20/2006	Michael Liebschner	1789-12403	6400
23505	7590	05/13/2008	EXAMINER	
CONLEY ROSE, P.C.			CHANG, VICTOR S	
David A. Rose				
P. O. BOX 3267			ART UNIT	PAPER NUMBER
HOUSTON, TX 77253-3267			1794	
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			05/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,415	Applicant(s) LIEBSCHNER, MICHAEL	
	Examiner Victor S. Chang	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-38,42,44,45,48 and 49 is/are pending in the application.
- 4a) Of the above claim(s) 25,28-38,42,44,45,48 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-24,26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/13/05, 2/19/08</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 7-27) in the reply filed on 3/27/2008 is acknowledged. Applicant further elected the composition species of claim 7, wherein the viscous component is a copolymer of poly(dl-lactic acid) and poly(ethylene glycol) of claim 12 and the inclusions are poly(paradioxanone) of claim 14. It should be noted that applicant's election of viscous component as a copolymer of poly(dl-lactic acid) and poly(ethylene glycol) is incommensurate with the specification, because the specification merely discloses

“poly(l-lactic acid) [PLLA], poly(dl-lactic acid) [PDLLA], poly(glycolic acid) [PGA], poly(lactic-co-glycolic acid) [PLGA], poly(paradioxanone), poly(dl-glycolic acid) [PDLGA], poly(propylene fumarate) [PPF], oligo(PEG fumarate) [OPF], poly(ethyleneglycol) [PEG], poly(caprolactone) [PCA], poly(hydroxybutyrate) [PHB], poly(hydroxy valerate) [PHV], poly(SA-HDA anhydride), poly(orthoesters), poly(phosphazenes), and copolymers of dl-lactic acid and dl-glycolic acid.”

For the present Office action, the elected viscous component is interpreted as copolymers of dl-lactic acid. Claims 7-24, 26 and 27 are elected. Claims 25, 28-38, 42, 44, 45, 48 and 49 are withdrawn.

Information Disclosure Statement

2. The information disclosure statement filed 3/27/2008 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the

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application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 7-15, 17, 19-21, 23, 24 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Dalal et al. [US 2003/0180376].

Dalal's invention relates to a bone replacement material. The material comprises porous β -tricalcium phosphate, biodegradable agents and binders [abstract; 0006]. The biodegradable agents selected from the group consisting of polyorthoesters, poly(L-lactide) (PLLA), poly(D,L-lactide) (PDLLA), polyglycolide (PGA), poly(lactide-co-glycolide (PLGA), poly(p-dioxanone), and co-polymers thereof [0073]. The binders are flowable at room temperature and are solubilized in warm or hot aqueous solutions and cross-linked [0089-0090]. Total porosity is in

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the range of 5-80% [0062]. The proportion of pore-forming agent is preferably 10-50 w% [0080].

For claims 7-12, 14, 15 and 27, Dalal teaches all the features of the claimed invention.

For claims 13, 17 and 19-21, since Dalal's teaching encompasses the same biodegradable polymer being used as viscous component and inclusions, the shapes of the inclusion is indistinguishable from the viscous component, i.e., portions of a single biodegradable polymer inherently read on the two claimed components, including various embedded shapes and sizes of the inclusions.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 16, 18, 22, 26 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dalal et al. [US 2003/0180376].

The teachings of Dalal are again relied upon as set forth above.

For claims 16 and 22, since the process limitations have not been shown on the record to produce a patentably distinct article, the formed articles are rendered *prima facie* obvious, and this limitations at the present time has not been given patentable weight.

For claim 18, within typical densities of component materials, the amount of volume percent of the inclusion is either anticipated by a single biodegradable (pore forming) agent of

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10-50 w%, or obviously provided by practicing the invention of prior art, dictated by the same end use.

For claim 26, since Dalal teaches the same end use of the claimed invention, a workable compressive strength is deemed to be either anticipated, or an obvious routine optimization, dictated by the same property requirements of end use.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S. Chang whose telephone number is 571-272-1474. The examiner can normally be reached on 7:00 am - 5:00 pm, Tuesday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on 571-272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Victor S Chang/
Primary Examiner, Art Unit 1794